

February 20, 1997

K964782

**SUMMARY OF SAFETY AND EFFECTIVENESS****Reference 807.92: Content and format of a 510(k) summary.**

- 1) Ms. Sandra A. Pavlovic  
Medrad, Inc.  
One Medrad Drive  
Indianola, PA 15051  
(412) 767-2400

FEB 25 1997

November 22, 1996

2) **Device Name:**

Trade/Proprietary Name: Medrad Contrast Holder  
Common/Usual Name: Contrast Holder  
Classification Name: Unknown

3) **Predicate Device Information:**

The Medrad Contrast Holder is compared to and is substantially equivalent to the EF Brewer IV Stand (K823270) as both devices are intended to hold IV/Contrast containers during examinations. Both the predicate device and the Medrad Contrast Holder have a hook assembly to hold the containers and are adjustable for height. The differences are that the Medrad Contrast holder is attached to the Injector mount and is made out of aluminum and stainless steel hardware that are compatible within an MR environment where as the EF Brewer IV Stand is free-standing and is made of chrome-plated steel.

4) **Device Description:**

The Medrad Contrast Holder will be used in conjunction with 510 (k) approved Medrad Injector systems. The Contrast Holder mounts to either a Medrad injector pedestal or the Counterpoise System (CS) by means of clamps that attach to the pedestal or CS.

The injector pedestal mounted Contrast Holder utilizes a two-section telescoping tube with a hand-turned knob to adjust the height. Two hooks are used to hang containers. One of the pedestal mounts uses two ring clamps to mount to the pedestal shaft. The other mounts to one of the pedestal legs and is supported by a clamp on the handle of the injector control unit.

The Contrast Holder for the CS uses a ring clamp to attach to the articulating counterbalance arm of the CS. A hook hangs vertically from the clamp.

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**4) Device Description: (contd.)**

An optional tray for holding accessories or bottles is available. The tray snaps into a clamp on the lower section of the telescoping tube and can be removed for cleaning.

**5) Intended Use:**

The Medrad Contrast Holders are an accessory device intended to be used in conjunction with Medrad injectors. The device is designed to aid in the transfer of common contrast media or flushing agents such as saline to the syringe. Users of this device are to be medical professionals trained in CT, MR, Angiographic Procedures, and are expected to have a good understanding of the events leading up to and including the use of the device. The Medrad Contrast Holder replaces the need for a separate contrast holder or Medrad Contrast Holder and is designed specifically for use with Medrad injectors.

**6) Technological Characteristics:**

There are no new technological characteristic differences between the Medrad Contrast Holder and the EF Brewer IV Stand. The most significant difference is that the Medrad Contrast Holder is made of an aluminum pole and non-magnetic stainless steel hooks and hardware allowing the device to be used in an MR environment. The EF Brewer stand is made of chrome-plated steel.

**Performance Data**

The Medrad Contrast Holder was tested by performing a visual inspection of the system as well as a functional evaluation that included adjustable height, magnetic interference, magnetic attraction, chemical resistance, rate of collapse, handling/tip testing, durability and life-cycle testing, support hook testing, installation testing and shipping and handling testing. These tests were performed while the Medrad Contrast Holder was attached to the injector pedestal and with the Contrast Holder both in the retracted and extended mode. The purpose of these tests was to ensure that 1) the device is safe and effective when used as intended, 2) that the contrast holder is compatible with the Medrad injector pedestals and could maintain a known weight of contrast containers and, 3) can be safely used in an MR environment. The Medrad Contrast Holder meets all specifications and passed all tests performed indicating that the device is safe and effective for its intended use.